

Information Disclosure Statement Transmittal

Docket Number

PENN0870US.NP

Address To
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

In Re Application Of:

Application No.	10/566,796
Filing Date	April 02, 2008
Examiner	Meller, Michael V.
Art Unit	1655

Title of Invention

Bowman-birk Inhibitor Compositions for Treatment of Muscular Atrophy and Degenerative Muscle Disease

BASIS FOR FILING (Select 1, 2 or 3 below.)

37 CFR 1.97(b)

- 1) ☐ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53 (d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

37 CFR 1.97(c)

- 2) ☒ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), but before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:

- a) ☒ the statement specified in 37 CFR 1.97(e);

OR

- b) ☐ the fee set forth in 37 CFR 1.17(p).

37 CFR 1.97(d)

- 3) ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(c), and on or before payment of the issue fee, and is accompanied by the Statement as specified in 37 CFR 1.97(e) and the fee set forth in 37 CFR 1.17(p).

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STATEMENT UNDER 37 CFR 1.97(e) ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The Information Disclosure Statement submitted herewith is submitted under one of the following conditions, which satisfies the requirement under 37 CFR 1.97(e). (Select 4 or 5 below if applicable.)

- 4) ☒ That each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or
- 5) ☐ That no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Remarks (Enter Remarks Below or Attach Document Containing Remarks)

Please see attached document containing remarks regarding references BF, BJ and BK.

Fee set forth in 37 CFR 1.17(p):

- ☒ No additional fee is required.
- ☐ A check in the amount of _____ is attached.
- ☐ The Director is hereby authorized to charge and credit Deposit Account No. 50-1619 as described below.
- ☐ Charge the amount of _____
- ☐ Credit any overpayment.
- ☐ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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Name	Kathleen A. Tyrrell	Registration Number	38,350
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<input type="button" value="eSign"/>	/Kathleen A. Tyrrell/	Date Signed	05/17/2011

Attorney Docket No.: PENN0870US.NP
Inventors: Sweeney et al.
Serial No.: 10/566,796
Filing Date: April 2, 2008

Remarks Regarding References BF, BJ and BK

The relevance of References BF, BJ and BK, as translated by the Japanese Patent agent in the corresponding Japanese patent application, is as follows:

Reference BF describes that BBI Is a serine protease inhibitor, which inhibits trypsin and chymotrypsin (see the last paragraph of right column on page 322, Figure 3 and Figure 5), having structural similarity with an inhibitor of cystein protease, bromelain. Reference BF does not describe any specific serine protease inhibitors other than trypsin and chymotrypsin among numerous serine protease inhibitors;

Reference BJ is a short review article, which describes that muscle from hereditary dystrophic human patients contains increase number of cells having elevated chymase activity, which is a class of serine proteins (see the first paragraph of left column on page 785). Reference BJ also describes that inhibition of chymase or its secretion might be of help to develop therapies for skeletal muscle myopathy (see concluding remarks on page 785). Reference BJ does not describe any name of specific chymase, while chymase comprise various family members such as granzymes, tryptases, elastases, cathepsin G, myeloblastin and chymase 1.

Reference BK is a short review article which describes that symptoms of Duchenne muscular dystrophy (DMD) are expected to be alleviated by inhibition of cysteine proteases such as calpains/CANP and cathepsins, or by serine proteases, since these proteases are hypothesized to be involved in dystrophic process of muscle DMS (see Figure 1 and lines 6-10 of right column on page 615). Reference BK does not describe any name of specific serine protease among numerous serine proteases.